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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ABBOTT LABORATORIES, an Illinois corporation, and LABORATORIES FOURNIER S.A., a French corporation,	:	Civil Action No. 08-05869
Plaintiffs,	:	Judge Joseph A. Greenaway, Jr.
v.	:	Magistrate Judge Madeline C. Arleo
TEVA PHARMACEUTICALS USA, INC.,	:	
Defendant,	:	

ANSWER AND DEFENSES OF DEFENDANT
TEVA PHARMACEUTICALS USA, INC.

Defendant Teva Pharmaceuticals USA, Inc.("Teva USA"), by and through its attorneys, herby answers the Complaint as follows:

THE PARTIES

Complaint Paragraph 1:

Plaintiff Abbot Laboratories ("Abbott") is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

Answer:

1. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1 of the Complaint, and therefore denies them.

Complaint Paragraph 2:

> Plaintiff Laboratories Fournier S.A. ("Fournier") is a French corporation having its principal place of business at 28 boulevard Clemenceau, 21000 Dijon, France.

Answer:

2. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint, and therefore denies them.

Complaint Paragraph 3:

> Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, PA 19454-1090.

Answer:

3. Admitted.

JURISDICTION AND VENUE

Complaint Paragraph 4:

> This Complaint is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, §§ 1 et seq.

This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

Answer:

4. Admitted.

Complaint Paragraph 5:

Venue properly exists in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

Answer:

5. Admitted for the purpose of this action only.

Complaint Paragraph 6:

Personal jurisdiction is proper in this district because Teva routinely transacts business in this district and the State of Illinois.

Answer:

6. Admitted for the purpose of this action only that personal jurisdiction is proper in the District of New Jersey.

FACTUAL BACKGROUND

Complaint Paragraph 7:

Fournier is the owner by assignment of U.S. Patent Nos. (a) 6,277,405 ("the '405 patent") (attached hereto as Exhibit 1), (b) 7,037,529 ("the '529 patent") (attached hereto as Exhibit 2), and (c) 7,041,319 ("the '310 patent") (attached hereto as Exhibit 3). The '405, '529, and '319 patents are collectively referred to herein as the "Patents-in-Suit."

Answer:

7. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 7 of the Complaint, and therefore denies them.

Complaint Paragraph 8:

> The '405 and '529 patents are titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It." The '319 patent is titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability."

Answer:

8. Teva USA admits that on their face United States Patent Nos. 6,277,405 ("the '405 patent") and 7,037,529 ("the '529 patent") bear the title "Fenofibrate Composition Having High Bioavailability and Method for Preparing It." Teva USA admits that on its face United States Patent No. 7,041,319 ("the '319 patent") bears the title "Fenofibrate Composition Having High Bioavailability."

Complaint Paragraph 9:

> Abbott is the exclusive licensee of the Patents-in-Suit.

Answer:

9. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 9 of the Complaint, and therefore denies them.

Complaint Paragraph 10:

> The Patents-in-Suit, which each expire on January 9, 2018, each claim novel fenofibrate compositions that exhibit a particular dissolution profile.

Answer:

10. Denied.

Complaint Paragraph 11:

> Fenofibrate is useful as a lipid and cholesterol lowering agent for treatment of adults with increased triglyceride levels.

Answer:

11. Admitted.

Complaint Paragraph 12:

Abbott has approval from the United States Food and Drug Administration ("FDA") to market fenofibrate tablets under the name TRICOR®.

Answer:

12. Admitted.

Complaint Paragraph 13:

TRICOR® (fenofibrate) is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's Abbreviated New Drug Application ("ANDA") to obtain approval of the ANDA applicant's drug product under provisions of 21 U.S.C. § 355(j).

Answer:

13. Admitted.

Complaint Paragraph 14:

The FDA's "Orange Book" also lists patents associated with approved drugs. The Patents-in-Suit are listed in the "Orange Book" in association with TRICOR® (fenofibrate).

Answer:

14. Admitted that the "Orange Book" lists the Patents-in-Suit that the Plaintiffs have asserted are associated with the TRICOR® fenofibrate product to the FDA. Denied as to the remainder of the allegations of Paragraph 14 of the Complaint.

Complaint Paragraph 15:

> Abbott and Fournier received a letter from Teva stating that Teva had filed an ANDA, designated as No. 90-069, requesting FDA approval to market a generic version of Abbott's TRICOR® tablets in 145mg dosage before the expiration of the Patents-in-Suit.

Answer:

15. Admitted that Teva sent Abbott and Fournier a letter stating that, *inter alia*, Teva had submitted to the FDA an abbreviated new drug application ("ANDA") seeking approval to engage in the commercial manufacture, use and sale of Fenofibrate Tablets, 145 mg before the expiration of the patents in suit. Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15 of the Complaint and therefore denies them.

ALLEGED INFRINGEMENT

Complaint Paragraph 16:

> 35 U.S.C. § 271(e)(2) provides that the submission of an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. Teva's submission of an ANDA for approval to sell fenofibrate tablets in 145mg dosages prior to the expiration of the Patents-in-Suit patent constitutes an act of infringement of one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2). In addition, Teva's generic version of TRICOR® (fenofibrate) infringes one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271.

Answer:

16. Teva USA admits that Teva USA's submission of an ANDA under 21 U.S.C. §355(j) for approval to sell fenofibrate tablets 145mg doses prior to the expiration of the Patents-in-Suit is deemed a technical act of infringement under 35 U.S.C. § 271(e)(2) to allow Plaintiffs, as alleged brand name drug manufacturers, to challenge Teva USA's ANDA application, and to allow Teva USA, as a generic drug manufacturer, to challenge the validity, unenforceability and infringement of the Patents-in-Suit. Teva USA denies each and every other allegation in Paragraph 16 of the Complaint.

Complaint Paragraph 17:

Plaintiffs have no adequate remedy at law to redress Teva's infringement.

Answer:

17. Teva USA denies each and every allegation in Paragraph 17 of the Complaint.

FIRST AFFIRMATIVE DEFENSE

18. The drug product for which Teva USA has filed its Abbreviated New Drug Application (ANDA) will not infringe any valid claim of the '405 patent.

19. The drug product for which Teva USA has filed its Abbreviated New Drug Application (ANDA) will not infringe any valid claim of the '529 patent.

20. The drug product for which Teva USA has filed its Abbreviated New Drug Application (ANDA) will not infringe any valid claim of the '319 patent.

SECOND AFFIRMATIVE DEFENSE

21. One or more claims of the '405 patent are invalid for failure to comply with one or more of the conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103 and/or 112.

22. One or more claims of the '529 patent are invalid for failure to comply with one or more of the conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103 and/or 112.

23. One or more claims of the '319 patent are invalid for failure to comply with one or more of the conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE

24. The '529 patent issued from a chain of patent applications. The first patent application in the chain was a French patent application No. 97 00479 (hereinafter the "'479 French application") filed on January 17, 1997.

25. The first United States patent application filed was U.S. Patent Application Serial No. 09/005,128 (hereinafter the "'128 patent application") and that application claims priority to the '479 French application.

26. United States Patent Application Serial No. 09/572,330 (hereinafter the "'330 patent application") was filed as allegedly a continuation of the '128 patent application. The '330 patent application issued as the '405 patent in suit.

27. United States Patent Application Serial No. 09/899,026 (hereinafter the "'026 patent application") was filed as allegedly a continuation of the '330 patent application. The '026 patent ultimately issued as the '529 patent in suit.

28. United States Patent Application Serial No. 10/078,500 (hereinafter the "'500 patent application") was filed as a continuation of the '026 patent application. Subsequently, United States Patent Application Serial No. 10/126,875 (hereinafter the "'875 patent application") was filed as a continuation of the '500 patent application.

29. United States Patent Application Serial No. 10/290,333 (hereinafter the "'333 patent application") was filed as a continuation of the '875 patent application. The '333 patent application ultimately issued as the '319 patent in suit.

30. Each of the '479 French application, the patent applications leading up to the patents in suit and the '405, '529 and '319 patents in suit identified as alleged inventors Andre Stamm and Pawan Seth.

31. On information and belief, Stamm and Seth, were fully aware that they were not the sole inventors of all of the subject matter claimed in the '128 application, and in later filed applications and patents in suit in the Stamm family, and knew that others at Fournier, with whom Stamm and Seth had collaborated, also should have been named joint inventors.

32. Nearly all of the '405, '529 and '319 patent claims asserted against Teva include the use of sodium lauryl sulfate as a dissolution medium. The only dissolution medium described in the French application is "a medium consisting of 1200 ml water to which 2% Polysorbate 80 is added, with a blade rotation speed of 75 rpm."

33. In contrast, after their collaboration with Fournier, on January 9, 1998 Stamm and Seth filed their '128 patent application that disclosed for the first time the use of 0.025 M sodium lauryl sulfate in water as a dissolution medium. Stamm and Seth continued that disclosure throughout the patent applications leading to the patents in suit.

34. On information and belief, neither Stamm nor Seth used 0.025 M sodium lauryl sulfate in water as a dissolution medium.

35. On information and belief, 0.025 M sodium lauryl sulfate was a preferred dissolution medium at Fournier. The 0.025 M sodium lauryl sulfate dissolution medium disclosed and claimed in the '405 and '529 patents was not invented by Stamm and/or Seth.

36. In filing their patent applications leading up to the '405, '529 and '319 patents in suit, Stamm and Seth filed with the United States Patent and Trademark Office declarations stating that they were the first and only inventors of the inventions claimed. Stamm and Seth knew that these declarations were material and false.

37. During the prosecution of the application that led to the '405 patent, the PTO rejected the application on the grounds of anticipation and obviousness based on an article by Temeljotov. In responding, Stamm and Seth emphasized that the claimed composition exhibited an improved dissolution profile compared to the dissolution profile of compositions of the prior art based, not on polysorbate 80 dissolution medium, but on the 0.025 M sodium lauryl sulfate in water dissolution medium in the claims.

38. Stamm and Seth argued that the claimed 0.025 M sodium lauryl sulfate dissolution medium was much more discriminating than 0.1 M sodium lauryl sulfate dissolution medium discussed in Temeljotov and that the 0.1 M sodium lauryl sulfate

dissolution medium was insufficient to differentiate fenofibrate-containing compositions because "almost any fenofibrate composition would show the type of dissolution profile described by Temeljotov." In response to this argument, the PTO allowed the claims that then issued in the '405 patent.

39. Throughout the chain of patent applications leading to the patents in suit, Stamm and Seth failed to take any steps to correct the inventorship of their patent application or to inform the PTO of other scientists' role in the claimed invention, despite ample opportunity to do so. Accordingly, the '405, '529, and '319 patents in suit were acquired by inequitable conduct and all of these patents are unenforceable.

WHEREFORE**,** Teva USA requests entry of judgment:

A. Dismissing Plaintiffs' Complaint with prejudice;

B. Denying all relief requested by Plaintiffs and any relief to Plaintiffs whatsoever;

C. That Teva USA has not infringed and is not infringing any valid and enforceable claim of the '405 patent, the '529 patent or the '319 patent;

D. That claims of the '405 patent, the '529 patent, and the '319 patent are invalid;

E. That the '405 patent, the '529 patent, and the '319 patent are unenforceable;

F. Awarding Teva USA reasonable attorneys' fees pursuant to, *inter alia*, 35 U.S.C. § 285;

G. Awarding Teva USA its costs of this action; and

H. Awarding to Teva USA such additional relief as this Court deems just and proper.

LITE DEPALMA GREENBERG & RIVAS, LLC

Date: December 18, 2008

/s/ Michael E. Patunas

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